REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-3 and 4-19 were in the application, claims 10-18 are withdrawn, claims 1-3, 4-9 and 19 have been cancelled, and new claims 20-28 have been added.

The examiner's comments on possible amendments to claims 10-18, if subject to rejoinder, will be taken into consideration once the composition claims in are allowable form.

Claims 2, 6, 9 and 19 were rejected as being indefinite for various deficiencies which have been addressed in replacement claims 21, 25, 27, and 28, and this rejection is believed to be moot.

Claim 20 replaces claim 1, clarifying that the invention is a "multiparticulate formulation", with more positive recitation of the components of the formulation.

The examiner objected to the amendment of the specification to describe the Eudragit® material as constituting "new matter". However, no new matter is involved.

The application, as filed identified that the coating group includes derivatives and polymers of acrylic and methacrylic acid. Specific coatings include Eudragit® L, Eudragit® RS, Eudragit® RL, which are commercially available examples of such polymers. Example 3.5 uses Eudragit® L30D, example 4.2 uses Eudragit® RS, example 4.3 uses RS and RL, and example 4.4 uses Eudragit® NE30D. The L, RS and RL materials have been identified by their scientific names in the specification and in claim 25.

The examiner must consider that these are pharmaceutical ingredients, and as such, due to the nature of regulation in the area, have a well defined meaning in the industry. These products have scientific names according to IUPAC regulations, which are relied on by those in the formulation industry and were known at the time of filing. Note that "[O]ne may refer to an element of a claimed invention held as a trade secret by name only and yet satisfy 35 U.S.C. §112 if equivalent elements are known, and known to be equivalents, and available to those skilled in the art, In re Gebauer-Fuelnegg, et al 28 C.C.P.A. 1359, 50 USPQ 125, 121 F.2d 505 (1941), White Consol Industries, Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 790 (Fed. Cir. 1983).

This case is also distinct from other trademark/trade name cases. The trade name has

specific grade designations that do identify the goods associated with the trademark. Such designations are not part of the trademark. See TMEP 1202.10 That is, "EUDRAGIT" is the trademark; it connotates source. The designations E, NE30D, L, L30D, S, FS, RL, RS and B, on the name chart provided to the examiner, are not part of the trademark, but grade designations which do identify specific products as containing a particular polymer substance.

The applicant identified not only the source for Eudragit®, but the product itself by use of the grade designation, and the applicant is now doing no more than providing the scientific names associated with these grade designations. As the ingredients are known by reference to the grade designations, the inclusion of the scientific names does not constitute new matter.

Claims 1-2, 5-6, 8-9 were rejected as being anticipated by Gai, et al. To have anticipation, each and every element of the claim must be found in a single prior art reference.

New claim 20 is directed to the multiparticulate formulation containing microgranules or microtablets. No such microgranules or microtables are found in Gai, rather, the formulation comprises two 300 mg tablets, each of which has a size of "11 mm, and a hardness of 6kg." This is a monolithic formulation, not a microparticulate formulation, as is the present invention.

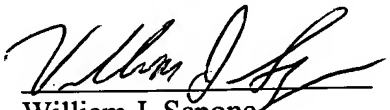
The structure is important to the invention as it contributes to providing the proper dissolution profile and one not found in Gai. An important use of the microgranules and microtablets is that these allow filling of capsules of different sizes to obtain dosages ranging from 50-800 mg/capsule. (Spec. P. 11). Thus, it is possible to dose into a capsule any proportion of microgranules to tailor the dosage and provide a smooth dissolutions profile based on clinical evaluation over a 24 hour period, something that cannot be achieved with the Gai tablet. As each and every element is not found in Gai, new claim 20, and the claims dependant therefrom are not anticipated thereby

Note that in Gai, there were differences between the release profiles of the "L" and "HP" tablets, due to diet and other variables which evidence variable dissolution over time. In fact, the L matrix showed poor bioavailability (P. 140), and this would lead one away from the present invention.

Based upon the above amendments and remarks, favorable consideration and allowance of the application is respectfully requested. However, should the examiner believe that direct

contact with the applicant's attorney would advance the prosecution of this application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



William J. Sapone
Registration No. 32,518
Attorney for Applicant(s)

Coleman Sudol Sapone P.C.
714 Colorado Avenue
Bridgeport, CT 06605
Telephone No. (203) 366-3560
Facsimile No. (203) 335-6779